K113504

510(k) Summary

FEB 0 1 2013

Submitter:	El.En. S.p.A. via Baldanzese, 17 50041 Calenzano (FI), Italy
Contact:	Paolo Peruzzi Regulatory Affairs Manager Phone: +39.055.8826807 E-mail: standards@elen.it
Date Summary Prepared:	January 30, 2013
Device Trade Name:	DEKA SmartXide^2 laser system and delivery accessories
Common Name:	CO_2 and Diode Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX, 21 CFR 878.4810
Equivalent Devices:	Lumenis UltraPulse Surgitouch (**K030147**) Quanta System Polysurge Diode Laser family (**K083613**) Biolitec 100W Ceralas Diode 980 nm model D100 (**K050824**)
Device Description:	The DEKA SmartXide^2 system is a medical laser system equipped with a 80W CO_2 laser source and an (optional) 980nm or 940nm 50W diode laser source. The CO_2 laser radiation has a wavelength of 10600nm and is delivered to the treatment area through an articulated arm and a delivery accessory connected to its distal end. The articulated arm is an optical assembly that delivers free beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO_2 laser beam to travel inside it and along its axis regardless of the arm orientation. An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations. The DEKA SmartXide^2 CO_2 laser can be used with DEKA CO_2 scanning units and the DEKA EasySpot Hybrid micromanipulator.

The scanning units move the beam on the tissue with controlled velocity and defined patterns to optimize the laser ablation.
The CO_2 laser focalized on very little spots by the micromanipulator and moved by scanning systems is useful to fasten the surgical procedures and limit the thermal damage to the tissues surrounding the ablation.

The diode laser source can be provided in two alternative wavelengths: 940nm and 980nm.
The diode laser radiation is delivered to the treatment area through optical fibers, which are guided to the target tissue with the aid of handpieces. The spot size is effectively the diameter of the fiber being connected to the system.

Emission parameters are selected on the front panel while laser emission is activated by a footswitch. The on-off switch and emergency switch are also located on the front panel of the system.

A warning light is located on the top cover, close to the control panel. Light ON state indicates that the system is enabled and ready.

Overall weight of the device is 95 kg, and the size is 210 cm x 59 cm x 56 cm (H x W x D).
Electrical requirement is 100-120Vac 50/60Hz, 220-230Vac 50Hz, 16A.

Indications for Use:

The DEKA SmartXide^2 CO_2 laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The DEKA SmartXide^2 940nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open surgery), cutting, vaporization, ablation and coagulation of soft tissues (endoscopic surgery) in medical specialties including: plastic surgery, dermatology, ENT, gynaecology, urology, general surgery, gastroenterology and dental procedures.

The DEKA SmartXide^2 980nm diode laser is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open and endoscopic surgery) in medical specialties including plastic surgery, dermatology, ear, nose and throat and oral surgery (otolaryngology), gynaecology, urology, neurosurgery, general and thoracic surgery, gastroenterology and dental procedures.

Comparison:	The DEKA SmartXide^2 laser system with its delivery accessories is substantially equivalent to its predicate devices. It shares same indication for use, same principle of operation and essentially same technological characteristics and performances.
Nonclinical Performance Data:	Bench test data and literature data have been provided in order to demonstrate that DEKA SmartXide^2, despite some differences in emission parameters, behaves as well as, or better than, the predicate devices. Several histological evaluations have been performed on three different animal tissues, in terms of ablation depth and lateral thermal damage; moreover literature data have been provided to support the DEKA SmartXide^2 safety and effectiveness for the claimed indications for use.
Clinical Performance Data:	None
Conclusion:	The tables of comparative features and the provided non clinical performance data show that the DEKA SmartXide^2 laser system with its delivery accessories is as safe and effective and performs as well as or better than the predicate devices, for the indications for use mentioned above.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EL.EN. Electronic Engineering SPA
% Mr. Paolo Peruzzi
Regulatory Affairs Manager and Offical Correspondent
17 Via Baldanzese
Calenzano, Italy 50041

February 1, 2013

Re: K113504
Trade/Device Name: DEKA SmartXide^2 laser system and delivery accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 08, 2013
Received: January 14, 2013

Dear Mr. Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(K) Number (if known): **K113504**

Device Name: **DEKA SmartXide^2 laser system and delivery accessories**

Indications for Use:

The DEKA SmartXide^2 **CO_2 laser** is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

The DEKA SmartXide^2 **940nm diode laser** is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open surgery), cutting, vaporization, ablation and coagulation of soft tissues (endoscopic surgery) in medical specialties including: plastic surgery, dermatology, ENT, gynaecology, urology, general surgery, gastroenterology and dental procedures.

The DEKA SmartXide^2 **980nm diode laser** is indicated for incision, excision, vaporization ablation and coagulation of soft tissues (open and endoscopic surgery) in medical specialties including plastic surgery, dermatology, ear, nose and throat and oral surgery (otolaryngology), gynaecology, urology, neurosurgery, general and thoracic surgery, gastroenterology and dental procedures.

Prescriptive Use ✓ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off)
Division of Surgical Devices
510(k) Number K113504

(Optional Format 1-2-96)